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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/777,789	02/11/2004	Birgit Oppmann	DX0935KC	4562

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DNAX RESEARCH INC.
LEGAL DEPARTMENT
901 CALIFORNIA AVENUE
PALO ALTO, CA 94304

EXAMINER

HAYES, ROBERT CLINTON

ART UNIT	PAPER NUMBER
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1649

MAIL DATE	DELIVERY MODE
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09/24/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/777,789	Applicant(s) OPPMANN ET AL.	
	Examiner Robert C. Hayes, Ph.D.	Art Unit 1649	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 July 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 31 and 33-52 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 31 and 33-52 is/are allowed.
- 6) ☒ Claim(s) 31 and 33-52 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Amendment

1. The amendment filed 7/2/07 has been entered.
2. The rejection of claims 31 & 33-49 under 35 U.S.C. 102(e) as being anticipated by Chang (U.S. Patent 5,741,772; IDS Ref # AB) is withdrawn due to the amendment of the claims.
3. Applicant's arguments filed 7/2/07 have been fully considered.
4. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Sequence Rules

5. This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CFR 1.821 through 1.825 because 37 CFR 1.821 (a)(2)(c-d) states that *each sequence disclosed must appear separately in the Sequence listing and in the text of the description and claims whenever described*. For example, the appropriate SEQ ID NOs must be recited on pages 23-24 for Table 2. See MPEP 2422 & 2431.

Applicant must comply with the requirements of the sequence rules (37 CFR 1.821 - 1.825). Note that failure to respond to both the requirements for sequence compliance and the Office action below will be held as nonresponsive, and may result in abandonment of this application.

Art Unit: 1649

6. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 50-52 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection.

No proper antecedent basis nor conception in context with that described within the specification at the time of filing the instant application exists for the binding affinities recited in claims 50-52 for generic antibodies. In contrast, page 46 of the specification contemplates these binding affinities for only monoclonal antibodies; thereby, constituting new matter for the broader scope now claimed.

It is noted that amending the dependency of claim 50 to claim 40, versus generic independent claim 31, should obviate this rejection.

7. Claims 31 & 33-52 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a written description rejection.

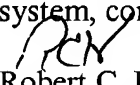
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The specification describes polyclonal and monoclonal antibodies, for example, on pages 35-37, 43-48 & 81, which include those having binding affinity to “specific domains, e.g., helices A, B, C or D of the IL-B60, or the Ig domain of the CLF-1” (pg. 44). Page 46 states that “[a]ntibodies may be agonistic or antagonistic...”. However, what exact epitopes distinguish an “agonist antibody or binding fragment” from an “antagonist antibody or binding fragment” has not been described (e.g., as it especially relates to claims 34 & 37). In fact, no antibodies of any type are described as being made, and/or deposited, as illustrated on page 81 where an invitation to “generate” polyclonal and monoclonal antibodies is alternatively stated. Therefore, although the specification reasonably describes making antibodies to the individual IL-B60 and CLF-1 polypeptides, no antibodies that “do not bind to SEQ ID NOs: 2, 4, 2 or 13 individually” are described, especially as it relates to making “agonist antibodies or binding fragments” and “antagonist antibodies or binding fragments”; thereby, not meeting the written description requirements under 35 U.S.C. 112, first paragraph.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to examiner Robert Hayes whose telephone number is (571) 272-0885. The examiner can normally be reached on Monday through Thursday from 9:00 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan, can be reached on (571) 272-0841. The fax phone number for this Group is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Robert C. Hayes, Ph.D.
September 11, 2007

ROBERT C. HAYES, PH.D.
PRIMARY EXAMINER